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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,472	09/07/2000	Eric S. Lander	2825.1027-0001	1705

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1655	7

DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/657,472	Lander et al
Examiner	**Art Unit**
Jehanne Souaya	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 7, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-72* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a method of diagnosing or aiding in the diagnosis of a vascular disease in an individual or predicting the likelihood that an individual will have a vascular disease by detecting a polymorphism at position 2210 of the thrombospondin 1 gene, classified in class 435, subclass 6.

II. Claims 17-19, drawn to a nucleic acid comprising all or a portion of SEQ ID NO 1, and wherein the nucleic acid comprises a polymorphism at position 2210 classified in class 536, subclass 23.1. gp 12/7/01

III. Claim 20, drawn to a peptide of SEQ ID NO 2 wherein the peptide comprises a serine at position 700, classified in class 530, subclass 380.

IV. Claims 21-30, drawn to a method of diagnosing or aiding in the diagnosis of a vascular disease in an individual by detecting a mutation at position 700 of the thrombospondin protein of an individual, classified in class 435, subclass 7.1.

V. Claims 31-46, drawn to a method of diagnosing or aiding in the diagnosis of a vascular disease in an individual or predicting the likelihood that an individual will have a vascular disease by detecting a polymorphism at position 1186 of the thrombospondin 4 gene, classified in class 435, subclass 6.

VI. Claims 47-49, drawn to a nucleic acid comprising all or a portion of SEQ ID NO 3, and wherein the nucleic acid comprises a polymorphism at position 1186 classified in class 536, subclass 23.1. gp 12/7/01

VII. Claim 50, drawn to a peptide of SEQ ID NO 4 wherein the peptide has a proline at amino acid position 387, classified in class 530, subclass 380.

VIII. Claims 51-60, drawn to a method of diagnosing or aiding in the diagnosis of a vascular disease in an individual by detecting a mutation at position 387 of the thrombospondin protein of an individual, classified in class 435, subclass 7.1.

IX. Claims 61-69, drawn to nucleic acids from the table, classified in class 536, subclasses 23.1 and 24.3. Applicant should note that if this group is elected, applicant must further elect a patentably distinct sequence from the table (see reasoning to follow, section 3).

X. Claim 70, drawn to a gene product encoded by a nucleic acid from the table, classified in class 530, subclass 380. Applicant should not that if this group is elected, applicant must further elect a patentably distinct sequence from the table (see reasoning to follow, section 3).

XI. Claims 71-72, drawn to a method of analyzing a nucleic acid from the table by determining a base occupying a polymorphic site from the table, classified in class 435, subclass 6. Applicant should not that if this group is elected, applicant must further elect a patentably distinct sequence from the table for practice with the method (see reasoning to follow, section 3).

2. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of groups II, VI, and IX are patentably distinct from the polypeptides of groups III, VII, and X, because they are drawn to different products having different structures and functions. The nucleic acids are composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptides are composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The nucleic acids and polypeptides can be used in materially different processes, for example the nucleic acids can be used in hybridization assays while the polypeptides can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups II, VI, and IX are patentably distinct from the polypeptides of groups III, VII, and X.

The methods of diagnosis and analysis of groups I, V, & XI and the nucleic acids of groups II, VI, & IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in recombinant methods to express proteins.

The polypeptides of groups III, VII, & X and the methods of diagnosis of groups IV & VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used

in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used to make fusion proteins with enzymatic functions.

The nucleic acids of groups II, VI, & IX and the diagnostic methods using protein based assays of groups IV & VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different modes of operation, requiring different reagents, reaction parameters, and reaction conditions; different functions, and different effects.

The polypeptides of groups III, VII, & X and the methods of diagnosis and analysis using nucleic acid based assays of groups I, V, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different modes of operation, requiring different reagents, reaction parameters, and reaction conditions; different functions, and different effects.

The methods of diagnosis and analysis using nucleic acid based assays of groups I, V, & XI and the methods of diagnosis using polypeptide based assays of groups IV & VIII are patentably distinct from each other the reagents, reaction parameters, and reaction conditions

needed to practice each invention are different. Further, the methods using nucleic acid based assays do not require the methods using protein based assays.

3. The nucleic acid sequences of groups II, VI, and IX are patentably distinct from each other. The polypeptides of groups III, VII, and X are also patentably distinct from each other. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Further, different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. It is noted that groups IX and X are drawn to nucleic acids and polypeptides from the table. The nucleic acids sequences from the table, as well as each distinct single nucleotide polymorphism, are patentably distinct from each other as they are structurally distinct chemical compounds and are therefore subject to restriction. Thus, if applicant elects either groups IX, X, or XI, applicant must further elect a distinct nucleic acid sequence including a single distinct SNP.

Further, the diagnostic and analytical methods of groups I, V, and XI are patentably distinct from each other as are the diagnostic methods of groups IV and VIII. Additionally, since the products of each group are patentably distinct, methods of using these products are patentably

distinct from each other since they are drawn to methods using different sequences and thus require different reagents, reaction parameters and reaction conditions.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XI, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Due to recent problems regarding the delivery and receipt of mail at the USPTO, applicant is advised to respond to this restriction requirement via facsimile, if possible. The fax phone number for this Group is (703) 305-3014.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1655

Dec. 7, 2001